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**STATE OF DELAWARE**  
**OFFICE OF CONTROLLED SUBSTANCES**

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<b>PUBLIC MEETING NOTICE:</b>	<b>CONTROLLED SUBSTANCE COMMITTEE</b>
<b>DATE AND TIME:</b>	<b>Wednesday, February 24, 2016 at 9:00 a.m.</b>
<b>PLACE:</b>	<b>Buena Vista Conference Center, Buck Library, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720</b>
<b>APPROVED:</b>	<b>April 27, 2016</b>

**MEMBERS PRESENT**

Art Jankowski, VMD, Veterinary Representative  
Philip Kim, M.D., Medical Representative  
Herb E. Von Goerres, R.Ph., Pharmacy Representative  
Stephen Ruggles, PA-C, PA Representative  
Mark Hanna, Public Representative

**MEMBERS ABSENT**

Michael Kremer, DMD, Dental Representative, President  
Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative  
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President  
Alex Zarow, R.Ph., Pharmacy Representative

**DIVISION STAFF/DEPUTY ATTORNEY GENERAL**

David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances  
Christine Mast, Administrative Specialist III  
Eileen Kelly, Deputy Attorney General  
Samantha Nettesheim, Pharmacist Administrator PMP  
Michelle McCreary, Pharmacist Compliance Officer

**ALSO PRESENT**

Tejal Patel, PharmD  
Hooshang Shanehsaz, R.Ph.  
Ray Hancock  
Debbie Hamilton  
Sean Moore  
Jeanne Chiquoine

**CALL TO ORDER**

Mr. Von Goerres called the meeting to order at 9:02 am.

**REVIEW AND APPROVAL OF MINUTES**

A motion was made by Dr. Kim, seconded by Dr. Jankowski, to approve the minutes for December 2, 2105. The motion was unanimously carried.

## **PRESIDENT'S REPORT**

No Report

## **UNFINISHED BUSINESS**

Non-Photo ID Cards – Ms. Kelly provided a draft of proposed amendments to Regulation 4.10 to include federal (military) ID's to 4.10.1.2 and language that would permit the obtaining of medications without ID in hospital discharge settings by adding an additional regulation 4.10.1.5. Dr. Kremer suggested language stating "immediately upon discharge" be added to 4.10.1.5. This addition will resolve the issues hospitals are experiencing however, this will not resolve the issues retail pharmacies experience with Non-Photo ID carriers. A motion to accept the proposed changes to regulation 4.10 and the addition of 4.10.1.5 with the changes discussed was made by Dr. Kim and seconded by Mr. Hanna. The motion Carried. A public hearing will be scheduled for April 27, 2016 for these proposed changes.

Proposed Changes §4735(b)-Patient Practitioner Relationship – Ms. Kelly presented proposed changes to the regulation. The committee reviewed the draft and stated that Section 1 of the draft was ok. Section 2 (b) should be added back in. Section 3 was ok. Ms. Kelly will make these changes and prepare the changes in bill form to present to Mr. Mangler, Director of the Division of Professional Regulation to acquire a sponsor for the changes. A motion was made by Dr. Kim seconded by Dr. Jankowski to accept the draft bill with the changes discussed. The motion unanimously carried.

Proposed Changes to Pharmacy Title 24 §2523 – a motion to table this topic until the Board of Pharmacy has made a determination was made by Mr. Von Goerres seconded by Mr. Ruggles. The motion unanimously carried.

## **NEW BUSINESS**

Review and Consideration of Hearing Officer Recommendation – Claudia Cannon, this agenda item was tabled until the April 27, 2016 meeting by Ms. Kelly Deputy Attorney General of the committee due to concerns of proper noticing of the licensee. A motion to table was made by Dr. Jankowski and seconded by Mr. Hanna. The motion Carried.

## **DIRECTOR'S REPORT**

### **Case/Diversion Review**

Mr. Dryden reported that he attended the NABP Law Enforcement Committee meeting as the Chair of the committee.

Mr. Dryden reported that there is a DEA continuing education opportunities on March 19-20, 2016 all are welcome to attend.

Mr. Dryden stated that Veterinarian inspections are currently occurring. Most veterinarians dispense drugs and well as store them. He is pleased to report that these inspections are going very well with very few issues or concerns to speak of.

## **Current Events**

### **CDC Reports Significant Increase in Opioid Overdose Deaths**

Prescription opioid pain relievers, such as oxycodone and hydrocodone, contribute to more overdose deaths than any other opioid type, according to new data from the Centers for Disease Control and Prevention (CDC). Overdose deaths related to such prescription opioids increased by 9% in 2014, accounting for 813 more deaths than in 2013.

Misuse and abuse of prescription opioid pain relievers and use of heroin are major factors contributing to the sharp rise in overdose deaths. Dependence upon or abuse of prescription opioids in the past year is the strongest risk factor for initiating heroin use, notes CDC. Findings indicate that opioid pain relievers and heroin were connected to over six out of 10 drug overdose deaths in 2014. To prevent overdose deaths, CDC recommends these four steps:

Provide tools and information, such as safer guidelines for prescribing opioid pain relievers, to help health care providers make more informed prescribing decisions.

Expand access to substance use disorder treatment, including Medication-Assisted Treatment, for people who suffer from opioid use disorder. Expanding access and use of naloxone to help protect people with opioid use disorder. Safeguard public health and safety by encouraging state and local public health agencies, medical examiners and coroners, and law enforcement agencies to work together to improve detection and response to illicit opioid overdose outbreaks.

#### *Doctors Are Unaware Patients Overdose on Prescription Opioids, Continue to Prescribe Opioids Afterward*

Over 90% of patients who survived an overdose from prescription opioids continued to receive prescriptions for the drugs after the overdose event, indicates a new report published in the December 28, 2015 issue of the *Annals of Internal Medicine*. These incidents occur because the doctors who prescribe the drugs often do not receive a record of the overdose from emergency departments, and patients who are dependent on opioids are less likely to report to their prescribing physician that they overdosed and were in the ER.

#### *Non-medical Use of Prescription Opioids Among Teens Increases Likelihood of Heroin Use*

The more frequently a teen uses prescription opioids for non-medical reasons, the higher the risk that he or she will become dependent on opioids, indicates a new study. Specifically, over 77% of teens who reported using heroin also reported using prescription opioids, indicates MedlinePlus. Joseph Palamar, lead researcher of the study, noted that teens who become dependent on prescription opioids often begin using heroin because it is cheaper and more available than illicit prescription pain pills. Further, nearly one-quarter of teens who reported taking prescription opioids over 40 times also reported using heroin.

#### *Robberies of Vans Delivering Drugs to Pharmacies and Hospitals On the Rise*

Robberies of vans or couriers that deliver drugs, primarily controlled substances, to hospitals and pharmacies are occurring more frequently, and tend to involve violence. Drivers of these delivery vans are usually alone, unarmed, and untrained on security measures, Drug Topics indicates. Further, Drug Topics notes that the Pharmaceutical Cargo Security Coalition reported at least 87 cases of theft from vehicles delivering drugs to pharmacies and hospitals in 2015. NABP convened a task force to examine strategies for preventing and reacting to pharmacy robberies and thefts in October 2014. The recommendations of the task force are available in a report on the NABP website.

#### *White House Announces Effort to Combat Heroin and Opioid Abuse in Rural Areas*

Department of Agriculture Secretary Tom Vilsack has been appointed by President Barack Obama to lead an interagency initiative to address heroin and opioid abuse, among other critical issues, in rural communities. The objective for Vilsack is to examine how resources across federal agencies can be invested in fighting the opioid abuse problem, reports The Washington Post. Since 2011, Vilsack has served as chair of the White House Rural Council, which consists of 15 departments and several agencies, including Health and Human Services, Veterans Affairs, and the Office of National Drug Policy, and he has witnessed the negative impact of drug abuse and poverty on rural communities. Approximately 30,000 people die from heroin and prescription opioid drug overdoses per year. From 2013 to 2014, heroin-related death rates rose by 28%. Over \$400 million in federal funds have been budgeted to address the opioid abuse epidemic; these funds are a \$100 million increase over last year.

#### *Food and Drug Administration Top Officials Call for Sweeping Review of Agency Opioids Policies*

In response to the opioid abuse epidemic, today Dr. Robert Califf, the Food and Drug Administration's Deputy Commissioner for Medical Products and Tobacco, along with other FDA leaders, called for a far-reaching action plan to reassess the agency's approach to opioid medications. The plan will focus on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief. The FDA will:

- \* Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;

- \* Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- \* Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- \* Develop changes to immediate-release opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- \* Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- \* Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- \* Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- \* Support better pain management options, including alternative treatments.

#### *President Obama Calls for Funding to Help Expand Access to Opioid Addiction Treatment*

President Barack Obama's 2017 budget calls for a twofold approach to address the prescription opioid abuse and heroin use epidemic. The president's budget seeks to expand access to treatment for prescription drug abuse and heroin use with \$1 billion in funding over two years. In addition, the budget seeks to expand state-level prescription drug overdose prevention strategies, increase the availability of medication-assisted treatment programs, improve access to the overdose-reversal drug naloxone, and support targeted enforcement activities with \$500 million in funding.

#### *DEA "360 Strategy" Aims to Address Prescription Opioid Abuse, Heroin Use, and Drug Trafficking With Pilot Program in St Louis*

Drug Enforcement Administration (DEA) continues to implement the "360 Strategy," a comprehensive plan to address prescription opioid abuse, heroin use, and related violent crime, by launching the pilot program in a second city, St Louis, MO. The 360 program launched in Pittsburgh, PA, in November 2015, and St Louis has been announced as the second pilot city, as noted in the [DEA press release](#). The "360 Strategy" seeks to break the cycle of drug trafficking, heroin and prescription drug abuse, and the violence that accompanies it, using a threefold approach. DEA's three objectives are as follows:

1. Offer leadership in law enforcement operations targeting drug trafficking organizations and violent gangs that supply drugs to local areas;
2. Engage manufacturers, wholesalers, prescribers, and pharmacists to raise awareness of the heroin and prescription drug abuse epidemic and advocate for responsible prescribing practices throughout the medical community; and
3. Provide communities with the tools necessary to fight the epidemic.

Further, the plan includes engaging different groups in the community to educate young people about the consequences of drug abuse and trafficking.

#### *USP Published Chapter on Handling Hazardous Drugs in Health Care Settings*

A new general chapter, <800> *Hazardous Drugs – Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the United States Pharmacopeia — National Formulary (USP—NF) by the United States Pharmacopeial Convention (USP) to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel (eg, physicians, nurses, veterinarians, pharmacists, and technicians) and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements, and have until July 1, 2018, to implement the new standard.

#### *Multifaceted Federal Bill Addressing Opioid Abuse Under Review by Legislators*

In response to the national epidemic of prescription opioid abuse and heroin use, a bill addressing prevention, education, law enforcement, and treatment efforts is under review in the United States Legislature. Among its many provisions, [Comprehensive Addiction and Recovery Act of 2015](#) (S 524), sponsored by Senator Sheldon Whitehouse (RI), would authorize funding to support state prescription

drug monitoring programs (PDMPs) and would require that PDMPs share data with other states. In addition, the bill would require states to expand or make available disposal sites for unwanted prescription medications. Further, the bill also includes provisions for training law enforcement officers in the use of naloxone and for the purchase of naloxone. The bill was sent to the Senate Committee on the Judiciary on February 11, 2016. An identical bill, the Comprehensive Addiction and Recovery Act of 2015 (HR 953) sponsored by Representative F. James Sensenbrenner, Jr (WI) was introduced in the Senate on February 12, 2015.

*Walgreens to Offer Over-the-Counter Access to Naloxone and Implement Drug Take-Back Program*

Walgreens will make naloxone, the opioid overdose reversal drug, available without a prescription at its pharmacies in 35 states and the District of Columbia, and the company will also install medication disposal kiosks in over 500 drug store locations in 39 states and the District of Columbia, by the end of the year. The naloxone program will roll out state by state throughout the year. The medication, administered by injection or nasal spray, became available without a prescription at Walgreens pharmacies throughout New York two weeks ago and will be introduced without a prescription in Indiana and Ohio later this month. The press release indicates Walgreens is willing to work with regulators in states where a prescription is mandatory to allow for dispensing naloxone without a prescription. The safe medication disposal kiosk program will allow individuals to conveniently dispose of their unwanted, unused, or expired prescriptions, including controlled substances and over-the-counter medications free of charge. The kiosks will be available during regular pharmacy hours, mainly at those open 24 hours a day. The installation of the kiosks began in California. Walgreens president of pharmacy and retail operations, Richard Ashworth, stated “Walgreens pharmacists play an important role in counseling patients on the safe use of their medications, and now we are leading the way in retail pharmacy’s fight against prescription drug abuse.” Delaware is NOT one of the 39 states mentioned above.

*Wilmington PDAC Open to Delaware Pharmacists*

Drug Enforcement Administration (DEA) invites Delaware pharmacists to participate in upcoming Pharmacy Diversion Awareness Conferences (PDACs) in Wilmington, DE. DEA is offering two regional one-day conferences, with one on Saturday, March 19, 2016, and another on Sunday, March 20, 2016. Each one-day conference is open to pharmacy personnel (pharmacists, pharmacy technicians, or loss-prevention personnel) who are employed by pharmacies or hospitals/clinics that are registered with DEA in Delaware. The conference is designed to help pharmacy personnel identify and respond to potential diversion activity. Location details, a conference agenda, and a link to the online registration form are available on the DEA website. There is no registration fee for these conferences. Upon completion of the one-day conference, pharmacists and pharmacy technicians may receive seven continuing pharmacy education hours (0.7 CEUs).

**PMP Review**

Ms. Nettesheim provided a power point presentation for review. The presentation explained the progress of the PMP as of this date.

**COMMITTEE REPORTS**

Medical Examiner’s Report

No report.

DEA Report

No report

Substance Abuse Report

No Report

Law Enforcement Report

Mr. Hancock reported that law enforcement is seeing an increase in Adderall diversion.

He also stated that during a recent investigation that he was requested to track down 2 prescription blanks that had been stolen. He had to explain that there is no possible way to track the 2 blanks based on information that is lacking on the prescription blank its self. The blanks have no specific identifying

serial number exclusive to that blank. These blanks have a current street value of \$500 to \$1000 dollars. He expressed the need to have serial numbers on the blanks so that they can be tracked and identified. He referred to §4798(4) in the statute and asked the committee to consider adding language to for the prescription blank to include an identifying serial number from the practitioner as well as the pharmacy prescription number. This would assist law enforcement in tracking of prescription blanks. This would also assist in reducing the time required to track these blanks. Alerts could also be sent to prevent stolen prescription blanks from being used thus preventing diversion.

Mr. Dryden stated that after the last meeting some research had been completed as requested regarding serial numbers on blanks and asked Ms. Nettesheim to report her findings.

Ms. Nettesheim stated that the Tamper Resistant Prescription Paper program was implemented to assist with the theft of prescription blanks. To implement a unique serial number for each blank would require significant costs. New York State has a unique serial number identifying prescription blanks. However, NY is currently in the process of phasing out the use of these blanks due to the integrity of the data returned. The data rate return in NY is currently only 20-40% return rate when searched. This is not cost effective. NY has now implemented statute that requires EPrescribing of all controlled substances.

Regulatory Committee Report

No Report

Legislative Committee Report

No Report

**INSPECTION REPORT**

Ms. McCreary reported that she has been working on a new opening of a methadone clinic here in the state.

**Dextromethorphan (DMX) Legislative Discussion**

CHPA - draft Model State Dextromethorphan Legislation – Ms. Deborah Hamilton and Mr. Sean Moore Associate Director, Consumer Healthcare Products Association presented information to the committee regarding the proposed legislation changes. Ms. Hamilton explained upcoming issues and concerns were discussed with stake holders. She stated that Pharmacy chain stores are neutral with their position of this legislation as well as grocery store chains. Mr. Moore discussed the affected population approximately of 5.25% of teens using dextromethorphan which has decreased to 3.1% in 2015. The legislation introduced would require the cashier to verify the age of anyone who appears to be under the age of 25 to ensure that the purchaser is at least 18 years of age.

**COMMITTEE CORRESPONDENCE**

None

**OTHER BUSINESS BEFORE THE BOARD**

None

**PUBLIC COMMENTS**

None

**EXECUTIVE SESSION**

None

**NEXT SCHEDULED MEETING**

The next regular meeting will be held on April 27, 2016 at 9:00 am at the Buena Vista Conference Center, Buck Library.

**ADJOURNMENT**

A motion was made by Dr. Kim, seconded by Dr. Jankowski, to adjourn the meeting at 10:30 am. The motion carried.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast  
Administrative Specialist III  
Office of Controlled Substances